DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. LEDESMA

Food and Drug Administration

[Docket No. 02D–0095]

Draft Guidance for Industry on Exposure-Response Relationships: Study Design, Data Analysis, and Regulatory Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Exposure-Response Relationships: Study Design, Data Analysis, and Regulatory Applications." The guidance is intended to provide recommendations for sponsors of investigational new drug applications (INDs) and applicants submitting new drug applications (NDAs) or biologics license applications (BLAs) on the use of exposure-response information in the development of drugs, including therapeutic biologics.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/

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ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lesko, Office of Clinical Pharmacology and Biopharmaceutics, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5690, or David Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION:

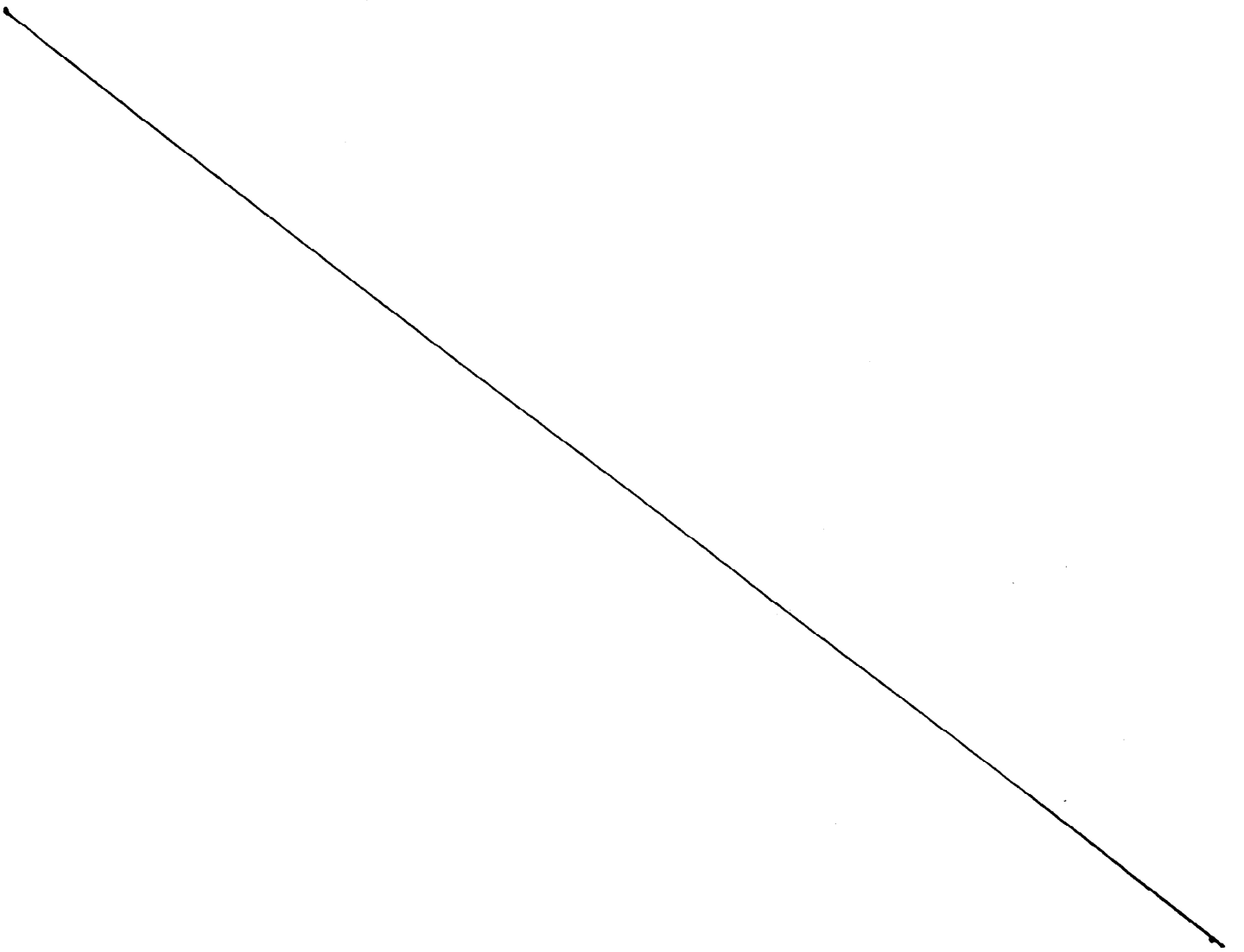
I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Exposure-Response Relationships: Study Design, Data Analysis, and Regulatory Applications." This guidance provides recommendations on the use of exposure-response information in the development of drugs, including therapeutic biologics. The guidance describes: (1) The uses of exposure-response studies in regulatory decisionmaking, (2) the important considerations in exposure-response study designs to ensure valid information, (3) the strategy for prospective planning and data analyses in the exposure-response modeling process, (4) the integration of assessment of exposure-response relationships into all phases of drug development, and (5) the format and content of reports of exposure-response studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on study design, data analysis, and regulatory applications of exposure-response relationships. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 3/25/02
March 25, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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